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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,612	09/15/2003	Gust H. Bardy	1201.1101102	2346
21691	7590	09/12/2006	EXAMINER	
CROMPTON SEAGER AND TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			MULLEN, KRISTEN DROESCH	
		ART UNIT		PAPER NUMBER
				3766

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,612	BARDY ET AL.	
	Examiner	Art Unit	
	Kristen Mullen	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 7/12/06 (Response).
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,38,40-42 and 44-52 is/are pending in the application.
 4a) Of the above claim(s) 52 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,38,40-42 and 44-51 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 15 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/15/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of invention I in the reply filed on 7/12/06 is acknowledged.
2. Claim 52 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Specification

3. The specification contains a reference to a commonly owned patent application by its application number. This application has since been issued. The examiner respectfully requests that the parent application information be updated in the specification along with any other referenced application numbers in the specification that have matured into patents.
4. The disclosure is objected to because of the following informalities: page 7, first paragraph, and last line: "mown".

Appropriate correction is required.

5. The abstract of the disclosure is objected to because it utilizes a phrase that can be implied ("is disclosed"). Correction is required. See MPEP § 608.01(b).
6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 40.
8. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

9. Claim 1 is objected to because of the following informalities: "a first and second ends". Appropriate correction is required.
10. Claim 47 recites the limitation "the anti-arrhythmia *biphasic* waveform" in line 2. There is insufficient antecedent basis for this limitation in the claim.
11. Claims 49 and 50 each recite the limitation "the electrically conductive surface" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 38, 40 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the parent application (09/663,606) was filed (9/18/00), had possession of the claimed invention. The claims as originally filed on 9/18/00 in the parent application do not contain the limitations of a cardioverter-defibrillator housing having “a downward taper continuously formed along at least one (an) exterior periphery” or “a pair of semi-converging tapers continuously formed about opposite sides of the downward taper”.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 44, 46, 48-49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,385,574).

Regarding claims 44 and 46, Hauser shows an implantable unitary subcutaneous cardioverter-defibrillator with an implantable canister providing a curved housing (see curved edges) enclosing and containing cardioversion-defibrillation circuitry, a pair of electrodes (70 or

62, 64) formed on opposite and facing ends of the housing and electrically interfaced via one or more conductors to the cardioversion-defibrillation circuitry (Figs. 8, 11, 16).

With respect to claim 48, Hauser shows monitoring circuitry (84) integral with the cardioversion-defibrillation circuitry and which derives physiological measures relating to QRS R-R interval stability (Col. 5, lines 27-39; Col. 6, lines 18-20, 22-25; Col. 7, lines 29-34).

Regarding claim 49, Hauser shows pacing circuitry (Col. 5, lines 27-39; Col. 7, lines 7-15, 25-35).

With respect to claim 51, Hauser further shows detection circuitry (84) (Col. 5, lines 31-36; Col. 6, lines 22-25; Col. 7, lines 29-35).

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. Examples of statements of intended use are:

- “to deliver an electrical therapy to the heart of a patient responsive to an autonomously detected arrhythmic condition”
- “to deliver an anti-arrhythmic waveform between the pair of electrodes to a heart of a patient responsive to an arrhythmic condition autonomously detected by the cardioversion-defibrillation circuitry”

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) as applied to claim 46 above and further in view of Ostroff (5,215,081). Hauser is as explained before. Although Hauser fails to specify the desirable range of voltages, energies (Joules), shock duration, and capacitance, attention is directed to Ostroff who teaches that the cardioversion-defibrillation energy is directly related to capacitance, shock duration, voltage, and resistance of the electrodes which in turn is dependent on electrode position and integrity (Col. 5, lines 50-56). It would have obvious to one with ordinary skill in the art at the time the invention was made to utilize the range of voltages, energies (Joules), shock durations, and capacitances set forth in the claim, since it is well known in the art that these factors are related to one another, and the ultimate energy delivered to the heart is dependent on these factors along with the resistance measured between the electrodes.

18. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) in view of Kroll (5,643,323).

Hauser shows an implantable unitary subcutaneous cardioverter-defibrillator with an implantable canister providing a curved housing (see curved edges) enclosing and containing cardioversion-defibrillation circuitry, a pair of electrodes (70 or 62, 64) formed on opposite and

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facing ends of the housing and electrically interfaced via one or more conductors to the cardioversion-defibrillation circuitry (Figs. 8, 11, 16).

Although Hauser fails to explicitly show induction circuitry, attention is directed to Kroll which teaches implantable defibrillators with induction circuitry are well known to be used to determine the defibrillation threshold for an implantable defibrillator (Col. 1, line 14-Col. 2, line 62). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hauser to include induction circuitry that generates low amplitude voltage on a T-wave as Kroll teaches in order to enable defibrillation threshold testing.

Double Patenting

19. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

20. Claims 1, 38, 40, 42 and 45 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 35, 69, 85 and 95 & 100 respectively of prior U.S. Patent No. 6,647,292. This is a double patenting rejection.

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

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application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 44, 46 and 47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 95, 100 and 99 (which includes the limitations of claim 95) of U.S. Patent No. 6,647,292.

For double patenting to exist as between the rejected claims and the patent claims, it must be determined that the rejected claims are not patentably distinct from claims 95, 100 and 99. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claims 95, 100 and 99 and, if so, whether those differences render the claims patentably distinct.

The difference between claims 44, 46 and 47 of the application and claims 95, 100 and 99 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific.

It is clear that all the elements of claims 44, 46 and 47 are to be found in claims 95, 100 and 99 (as it encompasses claim 95). Thus, the invention of claims 95, 100 and 99 of the patent is in effect a “species” of the “generic” invention of claims 44, 46 and 47 of the application. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*,

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29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 44, 46 and 47 are anticipated by claims 95, 100 and 99 of the patent, they are not patentably distinct from claims 95, 100 and 99.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kristen Mullen
Patent Examiner
Art Unit 3766

kdm

Kristen Mullen